

REMARKS

Claims 1-4, 7-15, 18-28, 30, 31, 34-37 and 47-50 are pending in the application. Claims 1, 10-12, 21-23 and 50 are currently amended. The amendments do not present any new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Applicable Obviousness Standards and Related Office Action Assertions

Applicant extends his appreciation to the Examiner for remarks concerning the basis for the obviousness rejections. Applicant respectfully submits the following remarks to further clarify what Applicant believes are the proper standards to support a rejection under §103(a).

Initially, to establish *prima facie* obviousness of a claim, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03. Additionally, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, *i.e.*, the prior art must suggest the desirability of the claimed invention. MPEP §2143.01, citing *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis).

Further, identification in the prior art of individual parts that are claimed is insufficient to defeat patentability of the whole claimed invention. *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP §2143.01 (emphasis added), citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Also, the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of a claim is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason, without the benefit of Applicant's specification, to make the necessary changes. MPEP §2144.04. Thus, whether a person skilled in the art "can" mix and match different components of different references is not sufficient.

Turning to the Office Action, the basis of the rejection (as best understood by the Applicant) is that a combination (mix and match) of components of different references based on "common sense" is proper, and that such "mixing and matching" of components is encouraged based on inherent motivation to all individuals skilled in the art to optimize a design. Office Action, p. 4, citing MPEP §2144.05, which cites *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

Applicant initially notes that MPEP §2144.05 is directed to “Obviousness of Ranges” of composition or process parameters such as temperature, concentration, weight, etc. The cited MPEP §2144.05 cites *In re Aller*, which involved claims reciting a temperature limitation of 100°C and a concentration of 10% compared to a prior art temperature range of 40-80°C and a concentration of 25-70%. The apparatus and system claims of the subject application, however, are not related to chemical compositions, related process or composition parameters, ranges of parameters, or optimization of such ranges of parameters. The cited section of the MPEP does not mention “apparatus” or “system” (or “common sense,” “mix,” or “match”).

Accordingly, Applicant respectfully submits that the basis presented in the Office Action does not (and cannot) properly support the claim rejections. If the claim rejections are nevertheless maintained following consideration of this Amendment, Applicant respectfully requests clarification of the grounds for such rejections be set forth in accordance with the appropriate “obviousness” guidelines for apparatus and system claims.

II. Claims 1-4, 7-15, 18-28, 30, 31, 34-37 and 47-50 Are Patentable Over Erb and Jahns

Having set forth the applicable obviousness standards, Applicant notes that independent claims 1, 12, 23 and 50 and respective dependent claims 2-4, 7-11, 13-15, 18-22, 24-28, 30, 31, 34-37 and 47-49 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,364,876 to Erb *et al.* (“Erb”) in view of U.S. Patent No. 6,558,382 to Jahns *et al.* (“Jahns”). Applicant respectfully submits that the cited references cannot support a rejection of these claims, especially as amended.

Initially, as implicitly acknowledged in the Office Action, Erb fails disclose, teach or suggest an apparatus or system having a “stimulation element” and a “stimulation energy sensing element” as recited in claims 1, 12 and 23, “means carried by the main body, for stimulating tissue” and “means, carried by the main body, for sensing stimulation energy” as recited in claim 50. As such, the Erb devices also lack a “non-coagulative stimulation element” as recited in claims 1, 12 and 23 and “non-coagulative means” as recited in claim 50. Further, Erb fails to disclose, teach or suggest a “connector [that is] located between the stimulation element and the stimulation energy sensing element” as recited in claims 1, 12 and 23. Jahns does not cure these deficiencies.

Jahns fails to disclose, teach or suggest “a non-coagulative stimulation element on the main body” as recited in independent claims 1, 12, 23 and 50. The Examiner relies on the electrode 422, electrode 522 and sensor 90 described by Jahns and asserts that the sensor 90 can

be sensing or stimulating. (Office Action, p. 2). Applicant respectfully submits that Jahns cannot support the rejection.

Initially, Jahns fails to disclose, teach or suggest a “non-coagulative” stimulation element as recited in claims 1, 12, 23 and 50. Instead, Jahns describes ablation electrodes 422 and 522. Jahns (col. 5, lines 55-60) (electrode 22 is placed near an end of the device 12 to be more easily manipulated against tissue 60 to be ablated); (col. 7, lines 59-63 (cooling electrode 22 used for ablation); col. 9, lines 16-17 (electrode 422 is placed on surface of the heart for ablation); col. 49-60 (needle electrodes 522 poke into tissue and ablation may occur as described above). Therefore, the electrodes 422 and 522 described by Jahns are not relevant to the pending claims, which recite a “non-coagulative stimulation element” and “non-coagulative” means.

The Examiner also takes the position that the sensor 90 described by Jahns is an electrode and is capable of both stimulation and sensing as recited in claims 1, 12, 23 and 50. Applicant must respectfully disagrees. As described by Jahns, the sensor 90 is used for sensing or detection and does not have the functionality of an electrode. For example, Jahns explains that the sensor 90 senses or detects temperature or another parameter. Jahns (col. 14, lines 55-57; col. 15, lines 14-39; col. 17, lines 18-19; col. 17, line 61 – col. 18, line 37). Nowhere does Jahns refer to the sensor 90 as an electrode. Further, nowhere does Jahns explain that the sensor is a stimulation element. Thus, it is clear that the sensor 90 is not an electrode and is not a “non-coagulative stimulation element” as recited in claims 1, 12 and 23, and is not a “non-coagulative” means as recited in the claim 50. This conclusion is consistent with the ordinary meanings of “sensor” and “electrode,” and the fact that Jahns refers to sensor 90 and electrodes 422 and 522 as different components, in a different context, and for performing different functions, facts which have not been addressed by the Office Action.

Moreover, Jahns discloses a suction / sensor embodiment having sensors 90, *i.e.* the embodiment illustrated in Figure 7, in which the sensors are along one side of the device, and the suction ports 786 are along the other side. Such an arrangement is, of course, very different than the claimed arrangement of “a connector located between the stimulation element and the stimulation energy sensing element” as recited in claims 1, 12 and 23.

Additionally, the electrodes 422 and 522 and the sensor 90 are components of different devices. Jahns explains that the system 10 can include a sensor 90 and describes and illustrates a first device, *i.e.*, an ablation device 12 that includes electrode 422 or needle electrodes 522. Jahns also describes a separate second device, *i.e.*, a sensor device 790, which includes sensors 90 and

suction ports 786. Jahns (col. 12, lines 62-66; Fig. 7). Notably, Jahns does not explain that the sensor device 790 includes electrodes. The Office Action, however, does not discuss or reconcile these differences, or the fact that the cited electrodes 422 and 522 and sensor 90 are different components of different devices used for different purposes.

Consequently, even if the asserted combinations are properly made, and Applicant does not concede that they are, such combination would nevertheless fail disclose each and every element of the claims. The rejection cannot stand based on these deficiencies alone. MPEP §2143.03 (to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art). In addition to these deficiencies, the required suggestion or motivation to combine the references and make the requisite substantial structural changes that would be required is lacking. The Office Action generally asserts that different components can be mixed and matched together, thereby rendering the claims obvious in view of the combination of Erb and Jahns. However, as discussed above, and Applicant respectfully submits that the simple fact that components “can” be combined cannot by itself support the rejection.

In addition to lacking disclosure of a connector and a stimulation element, and a sensing element placed on the sides of the connector, Jahns fails to disclose, teach or suggest why such a configuration would be desirable, particularly considering that Fig. 4 of Jahns illustrates an electrode 422 (but no stimulation or stimulation sensing element) along one side of the device, Fig. 5 illustrates needle electrodes 522 (but no stimulation or stimulation sensing element), and Fig. 7 of Jahns illustrates sensors 90 (but no stimulation or stimulation sensing element) along one side of a support surface 744, and suction ports 786 on another side of the support surface 744. The general, blanket assertion regarding “inherent optimization” in view of what is actually disclosed merely amounts to an assertion that different components “can” be combined, but this cannot support the rejection. The Office Action has not provided any other specific reasoning explaining why such substantial modifications and combinations would be desirable.

Otherwise, Jahns merely suggests using suction to secure a sensing device, which is not connected to an ablation device, to tissue. The fact that Jahns describes certain locations of electrodes 422 and 522 and the sensor 90 does not, without more, suggest adding a non-coagulative stimulation element and a stimulation energy sensing element and, in addition, arranging the stimulation and sensing elements with a connector there between. The various locations of the electrodes in Jahns (*e.g.* electrodes 522) would not have suggested anything to a

person skilled in the art concerning the addition and/or location of a “non-coagulative stimulation element” and a “stimulation energy sensing element” on the device described by Erb. Once again, such general, blanket assertions that modifications and combinations “can” be made cannot support the rejection.

Further, the required suggestion or motivation to modify Jahns is lacking in view of the significant structural changes that would be required, and Jahns teaches away from “a connector located between the stimulation element and the stimulation energy sensing element, the connector being configured to secure the coagulation element of the electrophysiology device within the main body adjacent to the suction region” as recited in claims 1, 12, 23 and 50 since the particular configurations described by Jahns involve an electrode on or extending outwardly from an outer surface of the ablation device. For example, Figure 5 illustrates needle electrodes 522 extending outwardly from a face 15. Jahns explains that such electrodes 522 are used for the particular purpose of poking through fatty tissue that covers the target tissue. Jahns (col. 9, lines 53-54). Such functionality would not be possible if the electrodes 522 were within the ablation device, and Jahns teaches away from the coagulation element “within the main body.”

Accordingly, Applicant respectfully requests that the rejection of independent claims 1, 12, 23 and 50 under §103(a) be withdrawn in view of the deficiencies of the cited references and the lack of the required suggestion or motivation to modify and combine the references.

III. Dependent Claims 2-4, 7-11, 13-15, 18-22, 24-28, 30, 31, 34-37 and 47-49 Are Patentable Over Erb and Jahns

Dependent claims 2-4, 7-11, 13-15, 18-22, 24-28, 30, 31, 34-37 and 47-49 incorporate the elements and limitations of respective independent claims 1, 12 and 23 and, therefore, are also allowable.

Further, Erb and Jahns, individually and in combination, fail to disclose, teach or suggest “wherein the suction region comprises a plurality of suction regions and the stimulation element comprises a plurality of stimulation elements” as recited in claims 2 and 13. Rather, Erb describes an antenna 23. The electrodes 422 and 522 are not relevant since claim 1 recites “non-coagulative” stimulation element, and the sensor 90 is not a stimulation element as discussed above. Similarly, Erb and Jahns also fail to disclose, teach or suggest “the stimulation element comprises a stimulation electrode” as recited in claims 3, 14 and 30 and “the stimulation element comprises a stimulation electrode pair” as recited in claims 4, 15 and 31.

Further, Jahns and Erb, individually and in combination, do not disclose, teach or suggest claims 7, 8, 18, 19, 34 and 35 in view of the deficiencies of the electrodes 422 and 522 and sensor 90 described by Jahns, the antenna 23 described by Erb, and Erb failing to disclose, teach or suggest stimulation and stimulation sensing elements as discussed above.

With regard to claims 9 and 20, the cited references may disclose multiple suction ports, but they do not disclose, teach or suggest multiple suction ports and, in addition, a connector, which is located between stimulation and stimulation sensing elements and between first and second suction ports. Jahns also fails to disclose, teach or suggest “the stimulation energy sensing element is adjacent to the first suction port” and “the stimulation element is adjacent to the second suction port” as recited in claims 10 and 21 in view of the deficiencies of the electrodes 422 and 522 and sensor 90 discussed above. Further, Figure 7 of Jahns only shows sensors 90 and suction ports 786.

Erb is deficient relative to claim 28, which recites “the electrophysiological device includes a plurality of spaced coagulation elements, the stimulation apparatus includes a plurality of spaced stimulation elements, and the electrophysiological device and stimulation apparatus are respectively configured such that the coagulation elements will be adjacent to respective stimulation elements when the electrophysiology device is connected to the stimulation apparatus.” In contrast, Erb refers to an antenna 23. Additionally, Jahns cannot support the rejection since the electrodes 422 and 522 and sensors 90 are not relevant to the claims, as discussed above.

Additionally, the electrodes 422 and 522 described by Jahns are not relevant to claims 47-49, which recite elements being “too small to form a transmural myocardial lesion.” In contrast, the electrodes 422 and 522 are used for ablation and forming a lesion. (Jahns, col. 5, lines 55-60; col. 7, lines 59-63; col. 9, lines 16-17; col. 49-60).

Accordingly, Applicant respectfully submits that dependent claims 2-4, 7-15, 18-28, 30, 31, 34-37 and 47-50 are also patentable over Erb and Jahns and respectfully request that the rejection be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and

remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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